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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,236	06/27/2001	Jeffrey H. Burbank	265/022	5534

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EXAMINER	
BIANCO, PATRICIA	

ART UNIT	PAPER NUMBER
3762	6

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AK

Office Action Summary	Application No. 09/894,236	Applicant(s) BURBANK ET AL.	
	Examiner Patricia M Bianco	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 June 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because of the following informalities: in line 4 the abstract reads "*the pump member. when*" which appears to be a grammatical error. Correction is required. See MPEP § 608.01(b).

2. Applicant has indicated co-pending applications in the first paragraph of the specification. The first page of the specification should be updated to clarify the status of all related applications noted in the first paragraph of the specification. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: reference number ***48*** on figure 7 is not in the specification as filed. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid

abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant states in claim 1 that the "*ratio of the clearance rate to blood flow rate is at least 100:400.*" It is unclear from the written description how this ration is met, since there is no support for a clearance to blood flow ration to be *100:400* in the specification.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 recites the limitation " *ratio of the clearance rate to blood flow rate is at least 100:400*" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-4, 6, 7, 10, 11 & 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falkvall et al. (5,730,712). Falkvall discloses an extracorporeal blood treatment apparatus and method of using to perform hemofiltration. The method of treating blood removed extracorporeally from a patient via hemofiltration comprises the steps of withdrawing blood through a withdrawal line at a rate of 400 mL/min or more, passing the blood through a filter, and returning the blood to the patient after treatment through a blood return line. This system and method allows for a urea clearance of 225 to 300 mL/min at this rate. With respect to claims 2, 6, & 10, the steps of repeating the

procedure at least four times a week, at least daily, and for more than one week would have been obvious to one having ordinary skill in the art since, lacking any criticality in the specification, the modifying of these steps for an individual's treatment schedule would depend on each patient and therefore vary on a per patient basis. With respect to claim 3, the recitation that the filter be disposable has not been given patentable weight since anything, if desired, can be disposable. With respect to claim 4 requiring the blood withdrawal and return lines and filter being pre-attached, it would have been obvious to one having ordinary skill in the art to use a cassette having pre-attached tubing and a filter since it has long been known in the art to use such cassette members for extracorporeal blood treatment procedures. With respect to claim 7, the step of conducting the procedure at home would have been obvious to one having ordinary skill in the art since, lacking any criticality in the specification, if home treatment is prescribed for a patient because it is deemed beneficial by the treating physician, this step would be determined on a per patient basis. With respect to claim 14, the use of a peristaltic pump for blood withdrawal and return would have been an obvious choice of a pump since it is known in the extracorporeal blood treatment art to use peristaltic pumps for blood withdrawal and return to a patient and Falkvall discloses that the filter is used with extracorporeal blood treatments.

7. Claims 1-11 & 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash (5,536,412). Ash teaches of a hemofiltration system and method for using comprising a patient connection including blood withdrawal and return lines, a filter, a

replacement/infusate fluid tank and delivery line, a pump, a blood particle sensor in the return line, and a sensor in the infusate line. The system pump rate is from 200 mL/min to 600 mL/min to achieve the desired clearance rate of 225 to 300 mL/min at this rate. The reservoir for infusate holds at least 1.5L of liquid. Ash has a computer for monitoring the blood flow rate and amount of infusate delivered to the patient. With respect to claims 2, 6, & 10, the steps of repeating the procedure at least four times a week, at least daily, and for more than one week would have been obvious to one having ordinary skill in the art since, lacking any criticality in the specification, the modifying of these steps for an individual's treatment schedule would depend on each patient and therefore vary on a per patient basis. With respect to claim 3, the recitation that the filter be disposable has not been given patentable weight since anything, if desired, can be disposable. With respect to claim 4 requiring the blood withdrawal and return lines and filter being pre-attached, it would have been obvious to one having ordinary skill in the art to use a cassette having pre-attached tubing and a filter since it has long been known in the art to use such cassette members for extracorporeal blood treatment procedures. With respect to claim 7, the step of conducting the procedure at home would have been obvious to one having ordinary skill in the art since, lacking any criticality in the specification, if home treatment is prescribed for a patient because it is deemed beneficial by the treating physician, this step would be determined on a per patient basis. With respect to claim 14, the use of a peristaltic pump for blood withdrawal and return would have been an obvious choice of a pump since it is known in the extracorporeal blood treatment art to use peristaltic pumps for blood withdrawal

and return to a patient and Ash discloses that the filter is used with extracorporeal blood treatments.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ash as applied to claim 1 above, and further in view of Loiterman et al. (5,041,098). Ash **discloses** the invention substantially as claimed, see rejection supra. Ash, however, fails to disclose specifically that the withdrawal and return lines are via a subcutaneous port.

Loiterman teaches of an implantable vascular access port that may be use din hemofiltration treatment systems. At the time of the invention, it would have been obvious to use an implantable vascular port in the process of Ash as taught by Loiterman. Use of an implantable port allows for easy connection and disconnection of the patient's vascular system to the hemofiltration system at each treatment.

Conclusion

9. Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers

for the organization where this application or proceeding is assigned is (703) 872-9302

for regular communications and for After Final communications (703) 872-9303.

Tricia Bianco
Patent Examiner
Art Unit 3762

pmb
September 5th, 2003